

food varying from the standard and to furnish such additional information as may be deemed necessary for action on the application.

(e) If the Commissioner concludes that the variation may be advantageous to consumers and will not result in failure of the food to conform to any provision of the act except section 403(g), a permit shall be issued to the applicant for interstate shipment of such food. The terms and conditions of the permit shall be those set forth in the application with such modifications, restrictions, or qualifications as the Commissioner may deem necessary and state in the permit.

(f) The terms and conditions of the permit may be modified at the discretion of the Commissioner or upon application of the permittee during the effective period of the permit.

(g) The Commissioner may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303(c) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary. The application for an extension shall be filed not later than 3 months prior to the expiration date of the permit and shall be accompanied by a petition to amend the affected food standard. If the Commissioner concludes that it will be in the interest of consumers to issue an extension of the time period for the market test, a notice will be published in the FEDERAL REGISTER stating that fact. The notice will include an invitation to all interested

persons to participate in the market test under the same conditions that applied to the initial permit holder, including labeling and the amount to be distributed, except that the designated area of distribution shall not apply. The extended market test period shall not begin prior to the publication of a notice in the FEDERAL REGISTER granting the extension and shall terminate either on the effective date of an affirmative order ruling on the proposal or 30 days after a negative order ruling on the proposal, whichever the case may be. Any interested person who accepts the invitation to participate in the extended market test shall notify the Commissioner in writing of that fact, the amount to be distributed, and the area of distribution; and along with such notification, he shall submit the labeling under which the food is to be distributed.

(j) Notice of the granting or revocation of any permit shall be published in the FEDERAL REGISTER.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related records are available for public disclosure when the notice of a permit or extension thereof is published in the FEDERAL REGISTER. Such disclosure shall be in accordance with the rules established in part 20 of this chapter.

(l) Any person who contests denial, modification, or revocation of a temporary permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[41 FR 38641, Sept. 10, 1976, as amended at 42 FR 4717, Jan. 25, 1977; 42 FR 15675, Mar. 22, 1977; 54 FR 18281, Apr. 28, 1989]

Subpart B—Food Additives in Standardized Animal Food

§ 564.20 Food additives proposed for use in animal foods for which definitions and standards of identity are established.

(a) Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the

provisions of the regulations in this subchapter E shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Commissioner publish notice of a petition for the establishment of a food-additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

(b) If a petition for a definition and standard of identity contains a proposal for a food-additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a food-additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this Subchapter E.

PART 570—FOOD ADDITIVES

Subpart A—General Provisions

Sec.

570.3 Definitions.

570.6 Opinion letters on food additive status.

570.13 Indirect food additives resulting from packaging materials prior sanctioned for animal feed and pet food.

570.14 Indirect food additives resulting from packaging materials for animal feed and pet food.

570.15 Adoption of regulation on initiative of Commissioner.

570.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

570.18 Tolerances for related food additives.

570.19 Pesticide chemicals in processed foods.

Subpart B—Food Additive Safety

570.20 General principles for evaluating the safety of food additives.

570.30 Eligibility for classification as generally recognized as safe (GRAS).

570.35 Affirmation of generally recognized as safe (GRAS) status.

570.38 Determination of food additive status.

AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

SOURCE: 41 FR 38644, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 570.3 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936 (52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 301-392).

(e) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. *Affecting the characteristics of food* does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) *Common use in food* means a substantial history of consumption of a substance by a significant number of animals in the United States.

(g) The word *substance* in the definition of the term *food additive* includes a food or feed or a component of a food or feed consisting of one or more ingredients.

(h) *Scientific procedures* include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.